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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,591	08/01/2003	Thomas B. Freeman	1372.50.PRC	1590

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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/604,591	FREEMAN ET AL.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 1/31/05.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/22/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 are pending.
Submitted Information Disclosure Statement (I.D.S) is noted.

Claim Rejections - 35 USC § 112

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: when to administer the vaccine, i.e. at the onset of infection, during or when, how much, and how many times, duration, etc.... This affects the dependent claims 2-7

Claims 1, 8, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the rabies vaccine composition, the ingredients i.e. additives (if any), adjuvant (if any), etc... The claims have been interpreted in light of the specification, however, since the disclosure is not enabling the claim is vague and indefinite. Claims 2-7 are affected, because they depend from claim1.

Claim 4 contains the trademark/trade name IMOVAX. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte*

Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a vaccine and, accordingly, the identification/description is indefinite.

In addition, Claim 4 is further vague and indefinite for recitation of "equivalent rabies vaccines thereof', what are these equivalent rabies vaccines? The claim has been interpreted in light of the specification, and since the specification does not set forth the intended "equivalent rabies vaccines", the claim is further vague and indefinite.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, or a substantial asserted utility or a well established utility.

The specification as filed does not disclose or provide any evidence that points to a "treatment of herpesvirus type 1 or type 2" by rabies vaccine. First, Applicants have not established any relationship between the two viruses. There is nothing in the disclosure that even remotely provides evidence for any activity against herpesvirus when rabies virus is administered. Applicant provides no credible teaching that what types of immune response would be induced whether it is TH1 or TH2 that lends itself to "treatment of infection" of

herpesvirus. There are no showings that MHC or humoral response against herpesvirus has been induced. There are no credible study either *in vivo* or *in vitro* present that would support the claimed invention. Prophetic statements do not provide credible and substantial teaching and is not patent eligible. Second, the story of three people that appear in the disclosure does not conform to the norms of scientific study design. There are no controls present. In other words, there are so many variables that have not been accounted for, such as any treatment(s) the subjects may have received after receiving the rabies vaccine, the serum antibodies that were present before the administration of rabies and after, any other compounds that were present in the vaccine composition that may have induced efficacy, etc... . In addition, the state of the art does not provide any teaching that there neutralizing antibodies induced against rabies cross react against herpes capsid proteins. Applicants are more than welcome to provide such evidence (emphasis added). Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be asserted.

Claims 1-9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, substantial, or a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. At the onset Applicant is reminded that the field of vaccine technology is highly unpredictable and absent clear and concise teaching by the Applicants one of ordinary skill in the art would be forced to conduct large quantity of undue experimentations to enable the claimed invention. The disclosure does not set forth any relationship between administration of rabies vaccine inducing protective efficacy against herpesvirus, there is no showing that administration of one vaccine would lead to "treatment" of herpesvirus. Applicants have general statements regarding the process of treatment against herpesvirus, wherein administration of a totally different virus i.e. rabies has supposedly a general efficacy in general population. However, the sample presented is rather small and statistically insignificant wherein a conclusion cannot be drawn, stories of three related people cannot be extrapolated to the population as a whole. Second, there is no animal model present that would establish the assertions made by the Applicants in the disclosure. Still further, Applicants have not considered the possibility of auto immunity when "vaccine is administered on an as need basis", thus, one of ordinary skill in the art would be forced to conduct large quantity of experimentation to enable the now claimed invention. In addition, Applicants make

all assumption in favor of their theory, without establishing the facts. For example, Applicants on paragraph 19, assert that the wife had lesion at the time of marriage and because the lesion was present before marriage, "it is not necessarily the same viral strain that was seen in patient #1 and may indeed represent a herpes Type 2 lesion", how can one draw such conclusion (emphasis added)? Where are the data that establishes such a fact? How can it be even concluded that the patient is infected with herpesvirus Type 2? Moreover, all three patients received IMOVAX Rabies vaccine, which is FDA approved, and yet, the claimed invention is directed to any and all rabies vaccine types having all types of adjuvants, attenuated as well as inactivated type, where administration would induce treatment against herpesvirus. The disclosure provides no working example for such a scope, and no data has been shared with the Office. Therefore, with regard to an unpredictable field, this does not constitute an adequate disclosure. See Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for development of a treatment for herpesvirus utilizing rabies vaccine. This means that the disclosure must adequately guide the art worker to enable the invention, without undue experimentation. The Applicant cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended

claimed invention. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988)*.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

6/01/2005